VOLUME-7, ISSUE-6, JUNE-2018 • PRINT ISSN No 2277 - 8160

Original Research Paper

Community Medicine

TO STUDY THE ADVERSE DRUG REACTIONS (ADR) & TO FIND OUT THE EFFECT OF ADR IN TB PATIENTS REGISTERED UNDER RNTCP IN KARAD TU.

Vandana Bhoi — Associate Professor, Department of Community Medicine, PIMS & R, Urun –Islampur, Maharashtra.

Anil Bhoi* — Associate Professor, Department of Paediatrics, PIMS & R, Urun -Islampur, Maharashtra. *Corresponding Author

ABSTRACT

BACKGROUND: Anti tubercular treatment (ATT) exhibit greater level of a efficacy with a satisfactory degree of toxicity, however combination treatment may produce severe adverse drug reaction (ADR). ADR leads to decrease in patient compliance & adherence .So close monitoring of ADR & it's effective management needed.

Objective- To study of adverse drug reactions (ADR) in tuberculosis (TB) patients registered under RNTCP and the effect of adverse drug reaction.

Material & Methods- This is longitudinal (Prospective) study done during January2008 to June2009 Total 806 patients who registered in 9 PHCs, Sub District Hospital, Krishna Hospital & 6DMCs with 3 ICTCs under Karad TU as study subjects.

Result & Observations - It was 513 (63.6%) patients had adverse reactions while 293 (36.35%) had no adverse reactions. Out of 513 patients 486 (60.30%)had gastritis, 33 (4.09%) had gastritis and joint pain, 49 (6.09%) had gastritis and skin rash, 62 (7.69%) had itching, 43 (5.33%) had joint pain. Thus gastritis was being the most common adverse Conclusion- There was no any significantly association seen between ADR and gender in this study. It was observed that 147(21.4%) patients continued DOTS treatment after giving treatment for ADR, 240(34.9%) continued DOTS treatment even if they were not treated for their ADR, 301(43.8%) continued DOTS treatment after given reassurance foe ADR.

Conclusion- Gastritis 480 (60.30%) was the most commonest adverse reaction seen as well as most of the adverse reactions was seen in intensive phase i.e. in first 2 months. There was not association in ADR and gender. In this study, 147(21.4%) patients continued DOTS treatment after giving treatment for ADR, 240(34.9%) continued DOTS treatment even if they were not treated for their ADR, 301(43.8%) continued DOTS treatment after given reassurance for ADR. Most of the adverse reactions were in intensive phase of treatment i.e. that in first 2 months. Gastritis was present in intensive phase as well as initial months of continuation phase treatment.

KEYWORDS : RNTCP, TU, ADR, TB.

Introduction:-

Tuberculosis is one of the oldest diseases known to mankind. Tuberculosis is probably the most important infectious disease in the world. It has been reported as one of the most important public health problem by all the regions of WHO[1].Due to steady increase in cases WHO declared in 1993 a state of global emergency against tuberculosis. Effective treatment against the disease has been available for over 60 years. Treatment requires a prolonged multidrug therapy which increases the potential risk of non-adherence by patients Tuberculosis is true indicator of social development[2]. If the person left untreated each person with active TB will infect on an average between 10-15 people every year. The circumstances have changed due to multi drug resistance of organisms and emergence of HIV/AIDS. HIV and AIDS have aggravated the tuberculosis burden. Considering above scenario the present research was undertaken alike various research done in this field.

Aim and Objective-

To study of adverse drug reactions (ADR) in patients registered under RNTCP and the effect of adverse drug reaction.

Material & Methods-

This is longitudinal (Prospective) study done during January2008 to June2009 Total 806 patients who registered in 9 PHCs, Sub District Hospital, Krishna Hospital & 6DMCs with 3 ICTCs under Karad TU as study subjects. Permission of District Tuberculosis Officer (DTO) taken before commencement of study. Patients were interviewed using semi structured questionnaires at their residence in defined time period i.e. at the start of treatment, after completion of IP and at the end of continuation phase.

Statistical Methods:

Analysis done by using appropriate techniques. Data was summarized in number and in percentage. Appropriate techniques used. Chi-square test was applied to assess statistical significance between variables.

Observations-Table1 : Time of Adverse Drug Reactions (ADR) occurrences

ADR	ADR			
	IP	CP	IP&CP	Total
	N (%)	N (%)	N (%)	N (%)
Gastritis	367(75.5%)	56(11.5%)	63(12.9%)	486(60.30%)
Red urine	262(76.8%)	39(11.4%)	40(11.2%)	341(42.31)
Itching	32(51.61%)	18(29%)	12(19.3%)	62(7.69%)
Burning in hands & feet	29(67.4%)	6(13.9%)	18(41.9%)	43(5.33%)
Joint pain	31(93.9%)	2(6.06%)	0(0%)	33(4.09%)
Impaired vision	2(20%)	8(80%)	0(0)	10(1.24%)
Loss of hearing	1(100%)	0(0%)	0(0%)	1(0.12%)
Ringing in ears	1(100%)	0(0%)	0(0%)	1(0.12%)
Dizziness & loss of balance	2(50%)	1(25%)	1(25%)	4(0.50%)
Jaundice	0(0%)	0(0%)	0(0%)	0(0%)
Skin rash	44(89.8%)	2(4.08%)	3(6.12%)	49(6.08%)
Gastritis + Red urine	262(76.8%)	39(11.4%)	40(11.7%)	341(42.30%)
Gastritis + joint pain	31(93.9%)	2(6.06%)	0(0%)	33(4.09%)
Gastritis, Dizziness & loss of balance	2(50%)	1(25%)	1(25%)	4(0.49%)
Gastritis + skin rash	44(89.8%)	2(4.08%)	4(8.16%)	49(6.07%)
No reactions				293(36.35%)

Table-2: Gender wise Adverse Drug Reactions

ADR	ADR Occurrence	Male N (%)	Female N (%)	χ2 value	P value
Gastritis	IP	220(75.1%)	147(76.2%)	0.091	0.956
	CP	34(11.6%)	22(11.4%)		
	IP&CP	39(13.3%)	24(12.4%)		
Red urine	IP	160(76.9%)	102(76.7%)	0.106	0.949
	CP	23(11.1%)	16(12%)		
	IP&CP	25(12%)	15(11.3%)		
Itching	IP	22(55%)	10(45.5%)	0.906	0.636
	CP	10(25%)	8(36.4%)		
	IP&CP	8(20%)	4(18.2%)		
Burning in hands& feets	IP	18(66.7%)	11(68.8%)	0.045	0.978
	CP	4(14.8%)	2(12.5%)		
	IP&CP	5(18.5%)	3(18.8%)		
Joint pain	IP	18(94.7%)	13(92.9%)	0.050	0.823
	CP	1(5.3%)	71(7.1%)		
	IP&CP	_	_		
Impaired vision	IP	1(16.7%)	1(25)	0.050	0.823
	CP	5(83.3%)	3(75)		
	IP&CP	_	_		
Loss of hearing	IP	1(100%)	_	0.104	0.747
	CP	_	_		
	IP&CP	_	_		
Ringing in ear	IP	1(100%)	_	0.104	0.747
	CP	_	_		
	IP&CP	_	_		
Dizziness &loss of balance	IP	1(50%)	1(50%)	2	0.368
	CP	0(0%)	1(50%)		
	IP&CP	1(50%)	0(0%)		
Jaundice	IP	_	_	_	_
	CP	_	_		
	IP&CP	_	_		
Skin rash	IP	28(90.3%)	16(88.9%)	0.169	0.919
	CP	1(3.2%)	1(5.6%)		
	IP&CP	2(6.5%)	1(5.6%)		
Gastritis + Red urine	IP	160(76.9%)	102(76.6%)	_	_
	CP	23(11.1%)	16(12%)		
	IP&CP	25(12%)	15(11.3%)		
Gastritis, Dizziness & loss of balance	IP	1(50%)	1(50%)	_	_
	CP	_	1(50%)		
	IP&CP	1(50%)	_		
Gastritis + skin rash	IP	192(73.3%)	131(74.9%)	_	_
	CP	33(12.6%)	21(12%)		
	IP&CP	37(14.1%)	23(13.1%)		
Gastritis + joint pain	IP	23(92.9%)	8(88.9%)	_	_
	CP	1(7.1%)	1(11.1%)		
	IP&CP	_	_		
No Reaction		171(58.4%)	122(41.6%)	_	_

Table3: Treatment of Adverse Drug reactions and DOTS treatment

Treatment of ADR	DOTS Treatment		
	T/t continued	T/t not continued	Total
Given	147(21.4%)	36(30.5%)	183(22.7%)
Not given	240(34.9%)	37(31.4%)	277(34.4%)
Reassurance	301(43.8%)	45(38.1%)	42.9%)
Total	688(100%)	118(100%)	806(100%)

$\chi 2 = 4.812$, df = 2, p = 0.090

Discussion:- In present study we have tried to find out various adverse reactions in tuberculosis patients who have been receiving DOTS and also their time of occurrence. It is observed that most of the reactions are in the intensive phase of treatment. One of the important aspects of regimen to be used in routine programme condition is the incidence of adverse reactions, but in our study commonest reaction has been gastritis which is present in intensive phase as well as initial phase of continuation phase of treatment. However hospitalization is not required in any patient with adverse reaction. Hence it can be concluded that the treatment is well tolerated by our patients. Hepatotoxicity has not been encountered by even single patients. Study conducted by Prasad R et al[3] and Rajeshwari R et al[4] found gastrointestinal symptoms 20%. In present study we have tried to find out various adverse reactions in tuberculosis patients who have been receiving DOTS and also their time of occurrence. There was no any significantly association seen between ADR and gender in this study. There was no significant association between ADR & gender in this study also there was no significant association between treatment of ADR & DOTS Treatment.

The other study has showed different adverse reaction. R Prasad et al[2] in addition found out of 89 patients, 18 (20.22%) suffered from GI upset,3(3.37%) had arthralgia,4(4.49%) had cutaneous reaction, one patient of hepatitis and one patient of peripheral neuropathy. Sukumaran P et al[5] have found out of total 100 patients, abdominal pain in 21 (21%), vomiting in 15 (15%), decreased appetite in 10 (10%) ,chest pain 3 (3%), while decreased sleep in 1 (1%) patient. In this study the patients having adverse drug reactions (ADR), have continued treatment. Some patients have reassured, some of them treated for ADR, some of them are not treated for ADR even though they continued and completed DOTS treatment. In this present study,346(42.9%) patients have reassured,183(22.7%) treated for ADR,277(34.4%) are not treated for ADR even though they continued and completed DOTS treatment. 147(21.4%) patients continued DOTS treatment after giving treatment for ADR, 240(34.9%) continued DOTS treatment even if they were not treated for their ADR, 301(43.8%) continued DOTS treatment after given reassurance for ADR.

Mark N. Lobato et al[6] found that out of 1211 patients 162 (13.37%) experience adverse effect, 66 (40.7%) had their treatment stopped permanently, 56(34.6%) patients completed treatment while 40 (24.7%) patients had other outcomes. Similar findings were found in study done by Athira B et al[7], Gholami K et al[8], , Tak DK et al[9], Abideen SP et al[10], Yee D, Valiguette C et al[11].

Conclusion- It was 513 (63.6%) patients had adverse reactions while 293(36.35%) had no adverse reactions. Most of the adverse reactions were in intensive phase of treatment i.e. that in first 2 months. Gastritis was present in intensive phase as well as initial months of continuation phase treatment. Out of 513 patients 486 (60.30%)had gastritis, 33 (4.09%) had gastritis and joint pain, 49 (6.09%)had gastritis and skin rash, 62 (7.69%) had itching, 43 (5.33%)had joint pain. Gastritis 480 (60.30%) was the most commonest adverse reaction seen .There was not association in ADR and gender.

References -

1) WHO. Sixth Report on the World Health Situation, Part 1.Geneva.WHO, 89, 1980.
2) Rajivir Bhalwar, Textbook of COMMUNITY MEDICINE, Walters Kluwer Publication, New Delhi, 2nd Edition 2018; 649.
3) Prasad R. ,Rizavi D M. , Surya Kant & Jain A. A comparison of unsupervised treatment along with intensive health education and Directly Observed Treatment in pulmonary tuberculosis. Int J Tub 2001; 48 :21 .
4) Rajeswari R., Chandrasekaran V., Suhadev M., Sivasubramaniam S., Sudha G & Renu G. Factors associated with patients and health system delays in the diagnosis of tuberculosis in South India. Int. J. Tuberc Lung Dis 2002; 6 (9): 789 – 795.
5) Sukumaran P., Venugopal K P & Rejoy Manjooran. A social study of compliance with DOTS. Ind J Tub 2002; 49:205.
6) Mark N. Lobato., Randall R Reves., Robert MJasmer.,John C Grabau., Naomi N Bock & Nong Shang. Adverse events and treatment completion for latent tuberculosis in Jail inmates and homeless persons Chest. 2005-217: 1296-1303.
7) Athira B., Manju CS., Jyothi E. A study on adverse drug reactions to first line antitubercular drugs in DOTS therapy. International Journal of Pharmacology and Clinical Sciences March 2015 Vol.4 Issue 1 7-11.

8) Gholami K., Kamali E., Hajiabdolbagh Mi & Shalviri G. Evaluation of antituberculosis induced adverse reactions in hospitalized patients. Pharmacy Practice 2006;4:134-8.
9) Tak DK. , Acharya LD. , Gowrinath K., Rao Padma GM & Subish P. Safety Evaluation Of Antitubercular Therapy Under Revised National Tuberculosis Control Programme In India. Journal of Clinical and Diagnostic Research 2009;3:1395-401.
10) Abideen SP., Chandrasekaran K., Maheswa-ran U., Vijayakumar A., Kalaiselvan V & Mishra A . Implementation of Self Re-porting Pharmacovigilance in Anti Tubercular Therapy Using Knowledge Based Approach. J Pharmacovigilance 2013; 1:101. doi: 10.4172/2329-6887.1000101.
11) Yee D., Valiguette C., Pelletier M., Parisien I., Rocher I & Menzeis D. Incidence of seri-ous side effects from First-line antituberculosis drugs among patients treated for Active Tuberculosis. Am J Resp Crit Care Med 2003:167;1472-7.